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FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
Jerry R. Grychowski	6298-449	6148	
	EXAM	INER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395		PATEL, NIHIR B	
	ART UNIT	PAPER NUMBER	
	3743		
		Jerry R. Grychowski 6298-449  EXAM PATEL, ART UNIT	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)		
Office Action Summer	10/774,751	GRYCHOWSKI ET AL.		
Office Action Summary	Examiner	Art Unit		
	Nihir Patel	3743		
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period or Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	l. ely filed the mailing date of this communication. O (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed on 11.2	<u>9.2005</u> .			
2a) ☑ This action is <b>FINAL</b> . 2b) ☐ This action is non-final.				
3) Since this application is in condition for allowa	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
<ul> <li>4)  Claim(s) 1-31 is/are pending in the application 4a) Of the above claim(s) 2 and 15-23 is/are w</li> <li>5)  Claim(s) 11-14 is/are allowed.</li> <li>6)  Claim(s) 1,3-9 and 24-31 is/are rejected.</li> <li>7)  Claim(s) 10 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/o</li> </ul>	ithdrawn from consideration.			
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Education of the Education of the drawing (s) be held in abeyance. See tion is required if the drawing (s) is objected to be a second or be	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority document</li> <li>2. Certified copies of the priority document</li> <li>3. Copies of the certified copies of the priority application from the International Burea</li> <li>* See the attached detailed Office action for a list</li> </ul>	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage		
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:			

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#### **DETAILED ACTION**

#### Response to Arguments

Applicant's arguments with respect to claims 1, 3-14 and 24-31 have been considered but are most in view of the new ground(s) of rejection.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 9, 24-27, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Farmer (US 2002/0069870). Referring to claim 1, Farmer discloses an apparatus that comprises a chamber housing 14 (see figure 1) defining an interior space and comprising an input end and an output end (see figure 1); a one way valve 16 positioned upstream of the interior space, the one way inhalation valve operative to permit a flow of gas into the interior space of the chamber housing (see figure 1 and page 2 paragraph [0022]); a first inhalation conduit 17 communicating with the output end of the chamber, the inhalation conduit adapted to transmit medication to the patient (see figure 1 and page 2 paragraph [0022]); a second inhalation conduit (see figure 1; the portion located next the one way valve 16) communicating with the input end of the chamber housing wherein the one-way inhalation valve is located in the second inhalation conduit, the second inhalation conduit comprising an oxygen intake line communicating with the one way inhalation valve; an exhaust conduit (see figure 1; the portion located just before the exhaust valve 21) communicating with the first inhalation

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conduit 17; and a one way exhaust valve 21 located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit.

Referring to claim 3, Farmer discloses an apparatus that further comprises pressurized metered dose inhaler 11 in flow communication with the chamber housing downstream of the one way inhalation valve (see figure 1).

Referring to claim 4, Farmer discloses an apparatus wherein the second inhalation conduit comprises an adaptor having an output end connected to the input end of the chamber housing an input end connected to the oxygen intake line, the adapter having the one-way inhalation valve disposed therein (see figure 1).

Referring to claim 9, Farmer discloses an apparatus wherein the first inhalation conduit comprises a mask 18 (see figure 1).

Referring to claim 24, Farmer discloses a method step that comprises transmitting oxygen from a gas source through a holding chamber and inhalation conduit to the patient during an inhalation sequence of a breathing cycle; introducing the medication into the holding chamber 14; preventing a substantial transmission of an exhaust gas into the holding chamber during an exhalation sequence of the breathing cycle; transmitting a substantially portion of the exhaust gas into an exhaust conduit during the exhalation sequence; and preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles.

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Referring to claim 25, Farmer discloses a method step of preventing the substantial transmission of the exhaust gas into the holding chamber during the exhalation sequence comprising creating a back pressure in the holding chamber.

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Referring to claim 26, Farmer discloses a method step of creating the back pressure in the holding chamber comprises providing a one-way valve between the gas source and the holding chamber, and preventing the flow of the exhaust gas from the holding chamber toward the gas source with the one way valve.

Referring to claim 27, Farmer discloses a method step of preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences comprises providing a one way valve in the exhaust conduit, and preventing the flow of the exhaust gas from the exhaust conduit to the inhalation conduit with the one-way valve.

Referring to claim 29, Farmer discloses an apparatus wherein the second inhalation conduit is isolated from and does not communicate with ambient air.

Referring to claim 30, Farmer discloses an apparatus wherein the oxygen intake line and the exhalation conduit are connected to a ventilator (see paragraph [0004]).

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### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 2002/0069870) in view of Bayron et al. (US 6,886,561). Referring to claim 6, Farmer discloses the applicant's invention as claimed with the exception of providing a valve member that is a center post valve member connected to the valve seat. Bayron discloses an apparatus that does provide a valve member that is a center post valve member connected to the valve seat (see column 5 lines 54-60). Therefore it would have been obvious to modify Farmer's invention by providing a valve member that is a center post valve member connected to the valve seat as taught by Bayron in order to have better control of gas delivery.

Referring to claim 7, Farmer discloses the applicant's invention as claimed with the exception of providing a blocking member that has at least one opening formed therein to permit flow of gases therethrough. Bayron discloses an apparatus that does provide a blocking member

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that has at least one opening formed therein to permit flow of gases therethrough (see column 5 lines 24-30). Therefore it would have been obvious to modify Farmer's invention by providing a blocking member that has at least one opening formed therein to permit flow of gases therethrough as taught by Bayron in order to have better control of delivery.

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Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,269,810) in view of Bird (US 6,581,600). Referring to claim 8, Brooker discloses the applicant's invention as claimed with the exception of providing an inhalation conduit that comprises an endotracheal tube. Bird discloses an interface apparatus and combination and method that does provide an inhalation conduit that comprises an endotracheal tube. Therefore it would have been obvious to modify Brooker's invention by providing an inhalation conduit that comprises an endotracheal tube as taught by Bird in order to provide better way of delivering the medication.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 2002/0069870) in view of Richardson et al. (US 6,279,574). Referring to claim 28, Farmer discloses the applicant's invention as claimed with the exception of providing WYE connector connecting the second inhalation conduit and the exhaust conduit. Richardson discloses an apparatus that does provide WYE connector connecting the second inhalation conduit and the exhaust conduit. Therefore it would have been obvious to modify Farmer's invention by providing WYE connector connecting the second inhalation conduit and the exhaust conduit as taught by Richardson in order to provide better way of delivering the medication.

### Allowable Subject Matter

Claims 11 through 14 are allowed.

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel January 24<sup>th</sup>, 2006

Henry ennett

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